



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**MEMORANDUM**

February 28, 2002

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**SUBJECT:** Propanil. Revised Residue Chemistry Chapter for the Reregistration Eligibility Decision; PC code 028201; DP Barcode D280854; Rereg. Case 0226.

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**THROUGH:** Alan Nielsen, Branch Senior Scientist  
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and

Chemistry Science Advisory Council (Chem SAC)  
Health Effects Division (7509C)

**TO:** Rich Griffin, Biologist  
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Health Effects Division (7509C)

**INTRODUCTION**

The reregistration of propanil is being supported by the Propanil Task Force, with members consisting of Dow AgroSciences and RiceCo L.L.C.. Along with the members of the Task Force, Syngenta Crop Protection; Helena Chemical Company; Agrilience, LLC; Drexel Chemical Company; Platte Chemical Company; Nufarm, Ltd.; Micro-Flo, LLC; and Gilmore Marketing and Development, Inc. have active end-use products registered on food/feed crops. Propanil formulation classes for food/feed uses include the dry flowable (DF), emulsifiable concentrate (EC), soluble concentrate liquid (SCL), flowable concentrate (FC), and a ready to use (RTU) formulation. These formulations are typically applied as broadcast treatments using ground or aerial equipment.

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Attached is the residue chemistry chapter for the reregistration eligibility decision for the selective potemergence herbicide, propanil. This information was compiled by Dynamac Corporation under supervision of RRB2. This review has undergone secondary review by RRB2 and has been revised to reflect current Agency policies.

### **EXECUTIVE SUMMARY OF CHEMISTRY DEFICIENCIES**

- Revision of product labels with use claims on rice should specify a 60-day PHI for grain.
- Product labels with use claims on barley, oats, and wheat should be modified to delete the feeding restrictions for the grazing of treated chop or cutting for green chop.
- Wheat hay data are required for the reregistration of propanil.
- Additional data for irrigation and potable water may be required for reregistration of propanil if the registrant is not willing to establish a 7-day retreatment interval for rice and a 30-day discharge interval for water in treated paddies following application of propanil to rice paddies.
- All labels with use directions on rice should be amended to specify restrictions against application to fields where catfish farming is practiced and draining water from treated fields into areas where catfish farming is practiced.
- All registered propanil labels should be revised to specify a 60-day plant-back interval for all rotational crops.

### **RECOMMENDATIONS**

To ensure that EN-CAS Analytical Method No. ENC-9/90 for tolerance enforcement on rice and wheat matrices is adequate, it will be forwarded to the Analytical Chemistry Branch for Agency validation.

The Pesticide Analytical Manual (PAM) Volume II lists a colorimetric method (designated Method II) for determination of propanil residues in/on rice matrices, eggs, milk, and animal tissues. The Agency no longer considers this colorimetric method to be suitable for enforcing propanil tolerances; however, the method EN-CAS Method No. ENC-9/90, with some modifications, has been deemed adequate to analyze samples of eggs, milk, and animal tissues. The Agency recommends that the registrant propose method EN-CAS Method No. ENC-9/90 with some modifications for tolerance enforcement method. The method should be radiovalidated and subjected to an Independent Laboratory Validation (ILV) trial in accordance with PR Notice 98/7.

The Agency recommends that the tolerance expression for the combined residues of the herbicide propanil, and its metabolites (calculated as propanil) for plant and animal commodities be revised to specify that the residues of concern are propanil and its related compounds convertible to 3,4-dichloroaniline (3,4-DCA).

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The established tolerances for rice bran and rice hulls presently listed under 40 CFR §180.274(a)(2), should be reassigned under 40 CFR §180.274(a) for the purpose of tolerance reorganization. These tolerances are duplicates of the established tolerances for the same commodities listed in 40 CFR §180.274(a)(1).

The established tolerances for rice mill fractions and rice polishings should be revoked because according to Table 1 of OPPTS GLN 860.1000 these commodities are no longer considered to be significant livestock feed items.

cc: Sherrie L. Kinard (RRB2), Propanil Reg. Std. File, Propanil Subject File, RF, LAN. RD/I: Propanil Team Review (08/29/2001), Chemistry Science Advisory Council (9/5/2001), A. Nielson (9/17/2001).

7509C: RRB2: S. Kinard: CM#2:Rm 722B: 703-305-0563: 2/28/2002.

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# PROPANIL

## REREGISTRATION ELIGIBILITY DECISION

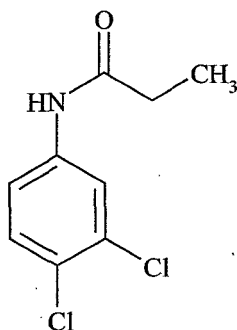
### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 028201; Case 0226

(DP Barcode TBA)

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## PROPANIL



### REREGISTRATION ELIGIBILITY DECISION

### RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 028201; Case 0226

### INTRODUCTION

Propanil (3',4'-dichloropropionanilide) is a selective postemergence herbicide registered on barley, oats, rice, and wheat for the control of broadleaf and grass weeds. Registered uses of propanil on barley, oats, and wheat are geographically limited to the states of MN, MT, ND, and SD whereas uses on rice are limited to the southern states (e.g., regions 4 and 6). The reregistration of propanil is being supported by the Propanil Task Force, with members consisting of Dow AgroSciences and RiceCo L.L.C.. Along with the members of the Task Force, Syngenta Crop Protection; Helena Chemical Company; Agrilience, LLC; Drexel Chemical Company; Platte Chemical Company; Nufarm, Ltd.; Micro-Flo, LLC; and Gilmore Marketing and Development, Inc. have active end-use products registered on food/feed crops. Propanil formulation classes for food/feed uses include the dry flowable (DF), emulsifiable concentrate (EC), soluble concentrate liquid (SCL), flowable concentrate (FC), and a ready to use (RTU) formulation. These formulations are typically applied as broadcast treatments using ground or aerial equipment.

### REGULATORY BACKGROUND

Propanil was the subject of a Reregistration Standard Guidance Document dated 12/23/87; the Residue Chemistry Science Chapter of the Guidance Document was dated 8/26/87. The Agency issued Data Call-In (DCI) Notices for propanil on 7/1/94 and 10/13/95. These documents

summarized the regulatory conclusions based on available residue chemistry data, and specified the additional data required for reregistration purposes. Several data submissions have been received and evaluated since the Guidance Document. The information contained in this document outlines the Residue Chemistry Science Assessments with respect to the reregistration of propanil.

Tolerances for residues of propanil in/on the grain and straw of barley, oats, rice, and wheat, in eggs and milk, in the fat, meat, and meat byproducts of cattle, goats, hogs, horses, poultry, and sheep, and in processed rice commodities (bran, hulls, mill fractions, and polishings) are established under 40 CFR §180.274(a)(1) and (a)(2). Propanil tolerances are expressed in terms of propanil and its "metabolites" (calculated as propanil). Adequate methods are available for data collection and tolerance enforcement. There are no Codex MRLs in effect for residues of propanil; therefore, there is no question with respect to Codex/U.S. tolerance compatibility.

## SUMMARY OF SCIENCE FINDINGS

### GLN 860.1200: Directions for Use

A search of the Agency's REFS database, conducted on 2/7/02, identified 37 active propanil end-use products (EPs) and 3 technicals registered under FIFRA Section 3 for use on food/feed crops. These EPs are listed below in Table A1. There are no Special Local Needs registrations associated with any member of the Task Force.

Table A1. Propanil EPs with Food/Feed Uses Registered to the Propanil Task Force <sup>1</sup>.

EPA Reg. No.	Label Acceptance Date <sup>2</sup>	Formulation	Product Name
<b>Syngenta Crop Protection</b>			
100-982	7/21/99	3 lb/gal EC	RiceCo Touche
100-1036 <sup>3</sup>	12/22/87	3 lb/gal EC	Arrosolo 3-3E
<b>Helena Chemical Company</b>			
5905-68	5/4/89	3 lb/gal RTU	Helena Brand Propanil-3
5905-77	6/5/89	4 lb/gal SC	Atlas Brand Propanil-4
5905-182	5/4/89	4 lb/gal EC	Helena Brand Propanil-4
5905-495 <sup>4</sup>	8/4/88	3 lb/gal EC	Setre Prowl Herbicide + Propanil
5905-523	3/31/97	79.2% DF	Propanil 60D
<b>Agrilience, LLC</b>			
9779-272	7/18/99	3.7 lb/gal EC	Propanil 4E
9779-306	7/18/99	60.0% DF	Propanil 60 DF
9779-338	5/14/96	3.7 lb/gal DF	Propanil 80 EDF
9779-340	4/10/96	59.6% DF	Londax Pro-Pack BNB
9779-343 <sup>5</sup>	2/21/97	79.2% DF	Pro-Pack 80EDF

EPA Reg. No.	Label Acceptance Date <sup>2</sup>	Formulation	Product Name
<b>Drexel Chemical Company</b>			
19713-30	1/31/94	3 lb/gal EC	Prop-Job 3 Propanil Herbicide
19713-31	2/24/94	4 lb/gal SC	Drexel Prop-Job 4 Propanil Herbicide
19713-285	5/17/94	4 lb/gal EC	IDA Prop-A-Nel 4
<b>Platte Chemical Company, LLC</b>			
34704-461	11/11/88	3 lb/gal EC	Best Propanil 3 EC Post Emergence Grass & Weed Killer
<b>Nufarm Ltd.</b>			
35935-2	12/89	3 lb/gal EC	Propanilo-3
<b>Micro-Flo Company, LLC</b>			
51036-233	2/1/95	4 lb/gal EC	Propanil 4EC
<b>Dow AgroSciences</b>			
62719-386	5/24/89	3 lb/gal EC	Stam® F-34 Herbicide
62719-389	5/24/89	3 lb/gal EC	Stam® LV-10 Herbicide
62719-392	7/29/96	4 lb/gal EC	Stam® M-4 Herbicide
62719-393	5/24/89	4 lb/gal EC	Stam® GX-4 Herbicide
62719-404 <sup>6</sup>	3/7/99	3 lb/gal EC	Stampede™ CM Herbicide
62719-413 <sup>7</sup>	1/7/98	81% DF	Stam® 80 EDF Herbicide
62719-436	2/23/98	80.2% DF <sup>8</sup>	Stampro™
<b>Gilmore Marketing and Development, Inc.</b>			
65656-2	6/15/98	80% DF	Rice-Nil DF 80
<b>RiceCo, LLC</b>			
71085-2	1/16/98	4 lb/gal EC	Blue Drum Herbicide
71085-3	1/16/98	3 lb/gal EC	Propanil 36
71085-4	6/95	50% DF	Propanil WDG
71085-5	1/16/98	4 lb/gal SC	Wham! EZ
71085-6	11/30/99	80% DF	Wham! DF 80 Herbicide
71085-9	2/20/96	4 lb/gal EC	Duet Herbicide
71085-13	4/94	60% DF	Propanil 60 DF
71085-16 <sup>9</sup>	9/21/00	80% DF	Duet EDF Herbicide
71085-20	3/31/00	4 lb/gal EC	Griffin Propanil 4E
71085-22	3/31/00	60% DF	Griffin Propanil 60 DF

<sup>1</sup> The Propanil Task Force consists of RiceCo L.L.C. and Dow AgroSciences.

<sup>2</sup> Date of the most recently EPA-approved label found in the product jacket or Pesticide Product Label System (PPLS).

<sup>3</sup> This product contains 3 lb/gal of propanil and 3 lb/gal of molinate.

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- 4 This product contains 3 lb/gal of propanil and 1 lb/gal of pendimethalin.
- 5 This product contains 79.2% of propanil and 0.6% of methyl-2-[[[[(4, 6-dimethoxy-2-pyrimidinyl)amino]carbonyl]sulfonyl]methyl]benzoate.
- 6 This product contains 3 lb/gal of propanil and 1.4 lb/gal of MCPA, 2-ethylhexyl ester.
- 7 This product contains 80.2% of propanil and 0.6% of bensulfuron methyl.
- 8 Product formulation is listed as soluble concentrate (SC) in REFs; however, upon examination of the product label, the formulation should be classified as a DF.
- 9 This product contains 80% of propanil and 0.62% of methyl-2-[[[[(4, 6-dimethoxy-2-pyrimidinyl)amino]carbonyl]sulfonyl]methyl]benzoate.

A comprehensive summary of the uses of propanil, based on the product labels registered to the members of the Propanil Task Force, is presented in Table A2. For the purpose of generating this Residue Chemistry Chapter, the Agency examined the registered food/feed use patterns and re-evaluated the available residue chemistry database.

Label amendments are required to incorporate the parameters of use patterns reflected in the submitted field trials. Details of the required label amendments are presented in the respective endnotes under GLNs 860.1500 (Crop Field Trials) and 860.1400 (Water, Fish, and Irrigated Crops) of Table B.



Table A2. Food/Feed Use Patterns Subject to Reregistration for Propanil (Case 0226, Representative Labels).

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Barley</b>							
Postemergence Broadcast Ground or aerial		3 lb/gal EC [62719-386]	1.13 lb/A	1	Not specified (NS)	NS	Use limited to spring barley grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Application may be made alone or as a tank mix with MCPA isooctyl ester. Treatment of barley beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>
		3 lb/gal EC [62719-404]	1.13 lb/A	1	NS	NS	Use limited to spring barley grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Treatment of barley beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>
		81% DF [62719-413]	1.13 lb/A	1	NS	NS	Tank mix use limited to spring barley grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Treatment of barley beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>

(continued; footnotes follow)

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1, 2</sup>
<b>Oats</b>							
Postemergence Broadcast Ground or aerial		3 lb/gal EC [62719-386]	1.13 lb/A	1	NS	NS	Use limited to oats grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Application may be made alone or as a tank mix with MCPA isooctyl ester. Treatment of oats beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>
		81% DF [62719-413]	1.13 lb/A	1	NS	NS	Tank mix use limited to oats grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Treatment of oats beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Rice</b>							
	Postemergence Broadcast Ground or aerial	3 lb/gal EC [62719-386]  4 lb/gal EC [62719-393]	6 lb/A	NS	8 lb/A	NS	Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground; 3 lb/gal EC), 20 (ground; 4 lb/gal EC), or 10 (aerial) gal of water/A. Applications are not permitted 45, 55, or 60 days after planting depending on the variety of rice. When double cropping is practiced, application to the second rice crop is prohibited. Applications are to be made when fields have been drained of most of the standing water and fields should be flooded within 12 to 24 hours of spraying. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Rice (continued)</b>							
	Postemergence Broadcast Ground or aerial	3 lb/gal EC [62719-389]	5 lb/A	NS	6 lb/A	NS	Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground) or 5 (aerial) gal of water/A. Applications are not permitted 28, 35, or 42 days after planting depending on the variety of rice. When double cropping is practiced, application to the second rice crop is prohibited. Applications are to be made when fields have been drained of most of the standing water and fields should be flooded within 12 to 24 hours of spraying. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

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Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Rice (continued)</b>							
	Postemergence Broadcast Ground or aerial	4 lb/gal EC [62719-392]	6 lb/A	NS	8 lb/A	NS	Use limited to rice grown in southern U.S. only. Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications are not permitted after the end of tillering depending on the variety of rice. Applications may be made alone or as a tank mix with other pesticides. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within 1/2 mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within 1/2 mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

(continued; footnotes follow)

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Rice (continued)</b>							
	Postemergence Broadcast Ground or aerial	81% DF [62719-413]	6 lb/A	NS	8 lb/A	NS	Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications are not permitted after the end of tillering depending on the variety of rice. Applications may be made alone or as a tank mix with other pesticides. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Rice (continued)</b>							
	Postemergence Broadcast Ground or aerial	80.2% DF [62719-436]	4.03 lb/A	NS	8.0625 lb/A	NS	Use limited to rice grown in AR, LA, MO, MS, and TX. Application should be made using a minimum of 15 (ground) or 10 (aerial) gal of water/A. Applications may be made alone or as a tank mix with other pesticides. <i>Do not graze treated fields or feed treated forage within 80 days of the last application.</i> * Use on wild rice ( <i>Zizania</i> spp.) is prohibited. Applications are to be made when fields have been drained of flood water and fields should be flooded within 24 hours of spraying. Application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced is prohibited. Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir.

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Site	Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Wheat</b>							
Postemergence Broadcast Ground or aerial		3 lb/gal EC [62719-386]	1.13 lb/A	1	NS	NS	Use limited to Durum wheat grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Application may be made alone or as a tank mix with MCPA isooctyl ester. Treatment of Durum wheat beyond the four-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>
			1.5 lb/A	1	NS	NS	Use limited to hard red spring wheat grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Application may be made alone or as a tank mix with MCPA isooctyl ester. Treatment of hard red spring wheat beyond the five-leaf stage is prohibited. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>



Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations <sup>1,2</sup>
<b>Wheat (continued)</b>						
Postemergence Broadcast Ground or aerial	3 lb/gal EC [62719-404]	1.13 lb/A	1	NS	NS	Use limited to Durum and hard red spring wheat grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Treatment of Durum wheat is prohibited beyond the four-leaf stage and of hard red spring wheat beyond the five-leaf stage. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>
	81% DF [62719-413]	1.13 lb/A	1	NS	NS	Tank mix use limited to Durum and hard red spring wheat grown in MN, MT, ND, and SD. Application should be made using a minimum of 10 (ground) or 5 (aerial) gal of water/A. Treatment of Durum wheat is prohibited beyond the four-leaf stage and of hard red spring wheat beyond the five-leaf stage. <i>The grazing of treated crop or cutting for green chop feed is prohibited.*</i>

The restricted entry interval (REI) for the 3 and 4 lb/gal EC (EPA Reg. Nos. 62719-392 and 62719-404) and 80.2% and 81% DF (EPA Reg. Nos. 62719-413 and 62719-436) is 24 hours.

<sup>2</sup> The following rotational crop restriction is established for the 80.2% DF (EPA Reg. No. 62719-436) formulation: "Do not rotate to crops other than rice for 120 days following application."

- All product labels with use claims on barley, oats, and wheat should be modified to delete the feeding restrictions for the grazing of treated chop or cutting for green chop.

#### GLN 860.1300: Nature of the Residue - Plants

The qualitative nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on rice and wheat. In plants, a majority of the radioactive residue is bound, either as dichloroaniline (DCA) conjugates or incorporated into natural constituents. A maximum of 26% of the residue in rice is quantitated using the enforcement method [i.e., as free- and base-releasable 3,4-dichloroaniline (3,4-DCA)]. In wheat, 34% of the straw residue and none of the grain residue is quantitated by the enforcement method.

The salient features of these plant metabolism studies along with the results of ruminant, poultry, and crayfish metabolism studies were presented to the HED Metabolism Committee on 1/16/96 (DP Barcode: D222631). Water metabolism was presented to the HED Metabolism Committee on 8/7/01. The Committee was asked whether propanil residues convertible to 3,4-DCA should remain the residues of concern in plants and livestock. The Metabolism Committee concluded that the residue to be regulated in plants and livestock is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites. A summary of the acceptable plant metabolism studies are presented below.

#### Rice (MRIDs 42382901, 42382902, and 43285401)

Uniformly ring-labeled [ $^{14}\text{C}$ ]propanil was applied to rice plants 23 days after planting, at an application rate of 3 lbs ai/A to the soil and 3 lbs ai/A foliarly. The total application rate was 6 lbs ai/A (0.75X the maximum rate permitted on registered labels). Rough rice grain was harvested at maturity 110 days after treatment, and processed into hulls, bran and milled rice. Straw was also harvested at maturity. Total radioactive residues were 0.234 ppm in the milled rice, 1.551 ppm in bran, 0.703 ppm in hulls, and 1.218 ppm in straw.

Rice matrices were solvent extracted, and the bound residues subjected to enzyme and chemical hydrolyses. Solvent extraction of rice matrices released only 8% of the radioactivity from grain, 15% from hulls, 26% from straw and 34% from bran. Protease and amylase hydrolysis released 62% of the grain TRR as starch-related compounds and 25% as protein-related compounds. For hulls, bran and straw, the largest fractions of the TRR were associated with hemicellulose and lignin. Radioactive residues were characterized/identified using TLC and HPLC. Residues identified in rice matrices included: propanil; 3,4-DCA; 3,4-dichloro-glucosylamine; and 3',4'-dichloroacetanilide. A total of 4.75% of the grain TRR was identified as radiolabeled glucose, thereby demonstrating that in rice, propanil is broken down and incorporated into natural components. Aqueous residues were identified as multicomponent polar moieties, consisting of sugars and conjugates with DCA.

#### Wheat (MRIDs 42209201 and 43372201)

Spring wheat was treated at 30 days after planting, when wheat was in the 2- to 3-leaf stage, with uniformly ring-labeled [ $^{14}\text{C}$ ]propanil at an application rate of 1.9 lb ai/A (1.25X the maximum registered rate). Grain and straw were harvested at maturity. Total radioactive residues were 1.31 ppm in straw and 0.16 ppm in grain. Grain and straw samples were solvent-extracted, and the bound residues subjected to sequential enzyme and chemical hydrolyses in order to determine how much radioactivity was associated with natural components such as proteins, starch, cellulose and lignin. After solvent extraction, approximately 70% of the TRR remained bound in both grain and straw. Following sequential hydrolyses, 42.5% of the straw TRR was associated with lignin, while 18.8% of the grain TRR was associated with lignin. Radioactive residues in wheat fractions were characterized or identified using TLC and HPLC. None of the grain radioactivity was conclusively identified. A total of 4% of the straw TRR (0.05 ppm) was identified as propanil; 4.1% (0.08 ppm) of the straw TRR was identified as 3,4-DCA, while an additional 1.04% TRR (0.02 ppm) was identified as N-(3,4-dichlorophenyl)-glucosylamine. Aqueous metabolites were partially characterized as polar, possibly sugars or conjugates with DCA.

Wheat grain and straw were analyzed using the proposed enforcement method. A total of 34% (0.68 ppm) of the straw TRR was quantitated as free- and base-releasable DCA. A total of 0% of the grain TRR was quantitated as DCA. Based on the available data, metabolites in wheat consist of DCA conjugates with natural components; incorporation of the radiolabel was not demonstrated.

#### GLN 860.1300: Nature of the Residue - Livestock

The qualitative nature of the residue in livestock is adequately understood based on acceptable ruminant and poultry metabolism studies. In livestock, significant metabolites such as 3',4'-dichloro-6'-O-sulfonic acid-acetanilide in the ruminant milk and liver, and 3,4-dichloroaniline-N-sulfamic acid in poultry liver, kidney, meat, skin and egg are not convertible to 3,4-DCA. A major portion of the residue in livestock, and certain bound residues in plants would not be included or quantitated using the enforcement method; therefore, the Committee was asked to confirm that propanil residues convertible to 3,4-DCA should be regulated in plants and livestock. Since the metabolites are in the detoxification pathway, it is likely that the metabolites will be excreted from the body more quickly than propanil or 3,4-DCA, the HED Metabolism Committee concluded that the residue to be regulated in plants and livestock is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites. Brief summaries of the available animal metabolism studies are presented below.

#### Ruminant (MRIDs 41848801 and 41983901)

Lactating goats were dosed with uniformly ring-labeled [ $^{14}\text{C}$ ]propanil at 53 ppm in the diet for five days. Total radioactive residues ranged from 0.068 ppm in the loin muscle to 1.856 ppm in

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the liver. Radioactive residues were solvent-extracted from milk, liver, kidney, fat, and leg and loin muscle. Solids remaining after extraction of the tissues were subjected to protease hydrolysis. Radioactive residues were identified or characterized using TLC and HPLC. Following extraction and hydrolysis, bound residues in the liver constituted 10.77% TRR, but were less than 4% TRR in all other tissues.

The principal residue identified in liver, muscle and fat was 3',4'-dichloroacetanilide, which constituted 29.4-48.8% TRR. The major metabolite in kidney was 3',4'-dichloroxaloanilide, at 36.41% TRR. Propanil, *per se* was identified in all tissues at 0.93-5.56% TRR, but was not found in milk. Principal residues in fat were 3',4'-dichloroacetanilide (42.4% TRR) and 3',4'-dichlorolactanilide (28.43% TRR); differences in the results for the two goats were attributed to a higher level of connective tissue in the fat of one goat. The principal metabolite in milk was tentatively identified as a dimer of propanil, connected by a C<sub>4</sub>H<sub>6</sub> bridge. Although identity of the metabolite was not confirmed, the registrant demonstrated that the metabolite is detected using the enforcement method. Other significant metabolites in milk were 3',4'-dichloro-6'-O-sulfonic acid-acetanilide (13.89% TRR) and 2-hydroxy-3',4'-dichloromalonoanilide (15.50% TRR).

#### Poultry (MRIDs 41754401 and 41755301)

White leghorn hens were dosed with uniformly ring-labeled [<sup>14</sup>C]propanil at approximately 50 ppm in the diet for seven days. Total radioactive residues ranged from 0.044 ppm in the egg white to 3.82 ppm in the liver. Tissues were solvent-extracted, and the remaining solids subjected to enzyme hydrolysis. Following extraction and hydrolysis, less than 5% of the TRR in all tissues remained as bound residues. Radioactive residues in tissues and eggs were characterized or identified using TLC and HPLC.

The predominant metabolites detected in hen tissues and eggs were 3',4'-dichloroacetanilide, 3,4-dichloroaniline-N-sulfamic acid, 3',4'-dichlorolactanilide, 3,4-DCA, and propanil. Metabolites that constituted greater than 10% of the TRR were 3',4'-dichloroacetanilide (found in eggs and all tissues except kidney tissue) and 3,4-dichloroaniline-N-sulfamic acid (found in all tissues and egg except fat). Dichloroaniline was not detected in thigh muscle and fat. Propanil, *per se* was detected in every tissue except breast muscle. The results of the metabolism study indicate that in poultry, propanil is metabolized to 3',4'-dichlorolactanilide and then to 3,4-DCA before conjugation with acetyl and sulfate moieties.

#### GLN 860.1340: Residue Analytical Methods - Plants and Livestock

Adequate residue analytical methods are available for tolerance enforcement and data collection. No additional data pertaining to this guideline topic are required for reregistration. The available methods for determining propanil residues of concern in/on plant and animal commodities are described below.

## Plants

A GC/NPD method (designated as EN-CAS Method No. ENC-9/90; earlier referred to as Method TR 34-93-99) has been submitted by Rohm and Haas. The method has been previously described and deemed adequate for data collection on rice and wheat matrices. It has been subjected to a successful independent laboratory validation (ILV) trial as required by PR Notice 96-1 and was adequately radiovalidated using  $^{14}\text{C}$ -labeled samples from the confined rotational crop study. To ensure that EN-CAS Method No. ENC-9/90 is adequate for tolerance enforcement, it will be forwarded to the Analytical Chemistry Branch for Agency validation.

A brief description of EN-CAS Method No. ENC-9/90 follows. Residues in/on plant matrices are hydrolyzed with 5 M NaOH converting parent propanil plus metabolites to their primary metabolite, 3,4-DCA. The hydrolysate is steam distilled for 16 hours using a Nielsen-Kryger apparatus, and the hexane and water fractions separated. The hexane fraction is then cleaned up on a silica gel column which has been pre-conditioned with hexane. The aqueous phase is washed with hexane, and the hexane wash added to the column. Residues are eluted from the column using hexane:ethyl acetate (75:25, v:v). Residues are quantitated using a GC equipped with a DB-17 or DB-1701 column and a nitrogen/phosphorous (N/P) detector. Residues are determined as 3,4-DCA, and calculated as the parent, propanil. This method has a limit of quantitation (LOQ) of 0.01 ppm, with a limit of detection of 0.003 ppm.

A GC method (MRID 00055547) was used in the analysis of certain plant commodities (barley and oats) discussed in the 8/26/87 Residue Chemistry Chapter. This method is similar to the GC method for propanil listed in the PAM Volume II (see "Livestock" section below) with the following exceptions: (i) a hydrolysis step that lasts 4 hours instead of 16 hours; (ii) use of a less caustic base (5 N NaOH instead of 25% NaOH); and (iii) residues of DCA are extracted into isooctane instead of hexane. The 8/26/87 Residue Chemistry Chapter reported that this method may recover **only** 40% of the residues recovered using the 16-hour hydrolysis in 25% NaOH required by Method II in the PAM Volume II.

The PAM Volume II lists a colorimetric method (designated Method II) for determination of propanil residues in/on rice matrices, eggs, milk, and livestock tissues. **The Agency no longer considers this colorimetric method to be suitable for enforcing propanil tolerances.**

## Livestock

The current preferred enforcement method is the GC/ECD method listed in PAM Volume II as Method I. The 8/26/87 Residue Chemistry Chapter reported that hydrolysis procedure used in this method (16 hours reflux distillation in 25% NaOH) has been shown to release ~55-65% of the total  $^{14}\text{C}$ -residues as DCA in milk and eggs collected from poultry and cows fed with ring-labeled [ $^{14}\text{C}$ ]propanil. The reported LOQ of Method I is 0.05 ppm.

An adequate GC/NPD method was used to analyze samples of eggs, milk, and animal tissues collected from the poultry and ruminant feeding studies. The method is based on EN-CAS Method No. ENC-9/90, described above for crop matrices, with some modifications. Briefly, residues of propanil are hydrolyzed with a 40% NaOH solution under reflux (overnight), cooled, and partitioned into hexane. Residues are partitioned into 2 N HCl, adjusted to pH 11, re-partitioned into hexane, and concentrated prior to analysis. Residues in milk, muscle, kidney, and liver are base hydrolyzed, steam distilled (overnight) into iso-octane, and cleaned-up on a silica gel SPE column eluted with hexane:ethyl acetate (1:1, v:v). Residues are determined as 3,4-DCA using a GC/NPD equipped with a DB-17 or DB-1701 column, and calculated as the parent compound. The LOQ for residues of propanil are 0.05 ppm in tissues (liver, kidney, muscle, and fat), 0.01 ppm in eggs, and 0.005 ppm in milk. **Should the registrant wish to propose this method for tolerance enforcement, it should be radiovalidated and subjected to an ILV trial in accordance with PR Notice 98/7.**

#### GLN 860.1360: Multiresidue Methods

The reregistration requirements for multiresidue method testing for residues of propanil and 3,4-DCA are satisfied. The 10/99 FDA PESTDATA database (PAM Volume I, Appendix I) indicates that propanil is completely recovered (>80%) using multiresidue methods PAM Volume I Sections 302 (Luke method; Protocol D) but is not recovered using Method 303 (Mills, Onley, and Gaither method; Protocol E) and 304 (Mills method for fatty food). There is a variable recovery of DCA using Method 302 (Luke method; Protocol D) and a small recovery (<50%) of DCA using Method 303 (Mills, Onley, and Gaither method; Protocol E).

#### GLN 860.1380: Storage Stability Data

The reregistration requirements for propanil storage stability data are fulfilled. Adequate storage stability data are available to validate the storage conditions and intervals of samples collected from crop field trials, processing studies, rotational crop, livestock feeding studies, and metabolism studies. Most samples were analyzed within the storage intervals and propanil residues have been determined to be stable.

#### Plants

Data reviewed in the 8/26/87 Residue Chemistry Chapter indicate that propanil residues are stable in frozen rice grain for 18 months, and in rice straw held at ambient temperature for 8 months. These data were generated using a Rohm and Haas colorimetric method which was deemed adequate for data collection purposes but not for enforcement purposes. Additional data reviewed after issuance of the 8/26/87 Residue Chapter indicate that residues (determined as 3,4-DCA and calculated as propanil) are relatively stable under frozen storage conditions (-27 to -23 °C) for up to 10 months in rice bran and polished rice, 18 months in rice straw, and

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20 months in rough rice grain and rice hulls. The data-collection method used to analyze storage stability study samples was EN-CAS Method ENC-9/90.

No supporting storage stability data were submitted with the wheat field trials; however, the treated wheat grain samples were stored 39 days prior to extraction, and extracts were analyzed for DCA residues three days later. Based on the short time interval between harvest and analysis, and based on the fact that samples were stored less than -20 °C during that time, no decline in propanil residues is expected to have occurred.

### Livestock

Samples collected from the poultry feeding study were stored frozen for 51 days for tissues or 118 days for eggs prior to residue analysis. Supporting storage stability data indicate that residues (determined as 3,4-DCA and calculated as propanil) are relatively stable under frozen storage conditions in the liver, muscle, and fat of poultry for at least 83 days, and in egg for at least 118 days.

Samples collected from the ruminant feeding study were stored frozen for 92 days for tissues and 126 days for milk prior to residue analysis. Supporting storage stability data indicate that residues (determined as 3,4-DCA and calculated as propanil) are relatively stable under frozen storage conditions in the liver, kidney, muscle, and fat of cattle for at least 127 days and in milk for at least 132 days.

Additional storage stability data indicate that residues of propanil and DCA-glucose are relatively stable in crayfish samples stored frozen for up to 18 weeks. These data are adequate to support the storage intervals and conditions of crayfish samples collected from the magnitude of the residue study.

### GLN 860.1500: Crop Field Trials

The reregistration requirements for data depicting magnitude of propanil residues for the following raw agricultural commodities are fulfilled: barley, grain; barley, straw; oat, forage; oat, grain; oat, straw; rice, straw; wheat, forage; wheat, grain; and wheat, straw. Overall, a sufficient number of field trials were conducted, and the trials were conducted using representative propanil formulations at the maximum registered application rates. In some cases, residue data were translated from an agronomically related crop group with identical use patterns. Label revisions are required for some crops in order to reflect current Agency policies and/or to reflect the parameters of use patterns for which field trial data are available. Details of the required label amendments are presented in the endnotes for respective crop sections under GLN 860.1500 (Crop Field Trials) of Table B.

Residue data for the aspirated grain fractions of wheat are not required because propanil is registered for use on wheat during the early vegetative stage (4- or 5-leaf stage or earlier) and nondetectable residues (<0.01 ppm) were observed in/on the RAC during the wheat grain study (conducted at 1X and 5X).

Additional data are required for wheat hay. The requested data for wheat hay will be translated to barley hay and oat hay.

Brief summaries of available propanil residue data, useful for tolerance reassessment only, are presented below.

### Cereal Grains Group

#### Barley and oat grains

Residue data (MRID 00078930) for barley and oat grains were reported in the 8/26/87 Residue Chemistry Chapter. Four tests were conducted in MN and six tests in ND in which barley or oats were treated with an EC formulation at 1.12-1.5 lb ai/A (~1X the maximum single and seasonal application rates) and harvested 60-82 days later. Residues in/on treated grain samples were nondetectable (<0.05 ppm). Samples were analyzed using the previously described GC method that employs a 4-hour sample hydrolysis in 5 N NaOH. The Residue Chapter determined that if the maximum conversion factor of 2.5 is used to calculate expected residue recovery using the 16-hour procedure, the maximum residues in grains (barley, oats, and wheat) would be 0.175 ppm; thus the established propanil tolerances for barley and oat grains were reassessed at the existing level of 0.20 ppm.

#### Rice grain

Two studies depicting magnitude of propanil residues in/on rice grain were submitted in response to the data gaps specified by the 8/26/87 Residue Chapter. In one study (MRIDs 42237101 and 42237201; DP Barcode D175886, 6/22/92, R. Perfetti), field trials were conducted in the states of AR, CA, LA, and TX. The 4 lb/gal EC formulation was applied at 4.0-8.0 lb ai/A (0.5-1.0X the maximum registered seasonal rate). Rice grain samples were collected at a 60-97 day PHI. The data-collection method used in the two studies was EN-CAS Method No. ENC-9/90, the proposed plant enforcement method. Propanil residues (determined as base-releasable 3,4-DCA) exceeded the established tolerance of 2 ppm in/on treated rice grain samples, and residues ranged from 0.03 ppm to 8.7 ppm.

In another study (MRID 43282801; DP Barcode D205676, 9/8/94, C. Swartz), field trials were conducted in AR, LA, and TX. Propanil residues (determined as base-releasable 3,4-DCA) ranged from 0.04 ppm to 2.20 ppm in/on rice grain harvested either 67 to 80 days following the last of two postemergence applications at 4 lb ai/A/application or 56 to 58 days following a single postemergence application at 6 lb ai/A. Based on the available data, the registrant had



been requested (DP Barcode D214322; 11/16/95, C. Swartz) to propose a revised tolerance, from 2 ppm to 10 ppm, for propanil residues in/on rice grain along with the establishment of a 60-day PHI.

#### Wheat grain and aspirated grain fractions

Wheat grain data (MRIDs 00055546 and 00111370) were reported in the 8/26/87 Residue Chapter. Ten tests were conducted in ND, seven tests in MN, one test in SD, and nine tests in Canada. Wheat plants were treated once with a representative EC formulation at 1.5-2.63 lb ai/A (~1.0-1.75X the maximum permissible label rate) using ground or unspecified equipment. Wheat grain samples were harvested 60-94 days following propanil application. Residues in/on treated grain samples were <0.05 ppm (nondetectable) from all tests except two Canadian tests in which residues were 0.06-0.07 ppm. Samples were analyzed using the GC method which included a four-hour hydrolysis in 5 N NaOH. The Residue Chapter determined that if the maximum conversion factor of 2.5 is used to calculate expected residue recovery using the 16-hour procedure, the maximum residues in grains (barley, oats, and wheat) would be 0.175 ppm. Samples collected from the MN tests were reanalyzed using Method II of PAM Volume II, and no residues were detected in/on wheat grain (as before).

Additional data (MRID 43196002; DP Barcode D203514, 9/22/94, C. Swartz) indicate that propanil residues (determined as base-releasable 3,4-DCA) were <0.01 ppm (nondetectable) in/on wheat grain samples harvested at maturity (87 days) following a single postemergence application of the DF formulation at either 1.1 or 5.5 lb ai/A (1X or 5X the maximum label rate). The data-collection method used was a GC/NPD method (EN-CAS Method No. ENC-9/90), which is also a proposed plant enforcement method. Based on the aggregate of data, the established tolerance for wheat grain is reassessed at its existing level of 0.20 ppm

As stated previously, residue data for the aspirated grain fractions of wheat are not required for reregistration.

#### Forage, Fodder, and Straw of Cereal Grains Group

##### Barley hay and straw

Barley hay data are not available. For the purpose of reregistration, the requested data for wheat hay will be translated to barley hay.

Barley straw data (MRID 00078930) were reported in the 8/26/87 Residue Chemistry Chapter. Four tests were conducted in MN and six tests in ND in which barley plants were treated with a representative EC formulation at 1.12-1.5 lb ai/A (~1X the maximum single and seasonal application rates) and harvested 60-82 days later. Residues in/on treated straw samples were <0.05-0.59 ppm following ground treatment and 0.04-0.019 ppm following aerial treatment. Samples were analyzed using the previously described GC method that employs a 4-hour sample

hydrolysis in 5 N NaOH. The Chapter determined that if the maximum conversion factor of 2.5 is used to calculate expected residue recovery using the 16-hour procedure, the maximum residues in straw would be 1.5 ppm; thus the established propanil tolerances for barley straw was reassessed from 0.75 ppm to 1.5 ppm.

#### Oat forage, hay, and straw

Oat forage and hay data are not available. For the purpose of reregistration, the available data for wheat forage will be translated to oat forage, and the requested data for wheat hay will be translated to oat hay.

Oat straw data (MRID 00078930) were reported in the 8/26/87 Residue Chemistry Chapter. Four tests were conducted in MN and six tests in ND in which oat plants were treated with a representative EC formulation at 1.12-1.5 lb ai/A (~1X the maximum single and seasonal application rates) and harvested 60-82 days later. Residues in/on treated straw samples were <0.05-0.59 ppm following ground treatment and 0.04-0.019 ppm following aerial treatment. Samples were analyzed using the previously described GC method that employs a 4-hour sample hydrolysis in 5 N NaOH. The Chapter determined that if the maximum conversion factor of 2.5 is used to calculate expected residue recovery using the 16-hour procedure, the maximum residues in/on straw would be 1.5 ppm; thus the established propanil tolerances for oat straw was reassessed from 0.75 ppm to 1.5 ppm.

#### Rice straw

The 8/26/87 Residue Chapter reported of tolerance-exceeding residues in/on treated rice straw samples collected from MS and CA which the registrant attributed to spray drift from other applications. To assess the adequacy of the established tolerance, the Chapter requested additional data. In response, the registrant submitted two studies. In one study (MRID 42237301; DP Barcode D175886, 6/22/92, R. Perfetti), field trials were conducted in the states of AR, CA, LA, and TX. The 4 lb/gal EC formulation was applied at 4.0-8.0 lb ai/A (0.5-1.0X the maximum registered seasonal rate). Rice straw samples were collected at a 60-day PHI. The data-collection method used in the two studies was EN-CAS Method No. ENC-9/90, the proposed plant enforcement method. Propanil residues (determined as base-releasable 3,4-DCA) did not exceed the established tolerance of 75 ppm in/on treated rice straw samples, and residues ranged from 0.08 ppm to 19.0 ppm.

In another study (MRID 43282801; DP Barcode D205676, 9/8/94, C. Swartz), field trials were conducted in AR, LA, and TX. Propanil residues (determined as base-releasable 3,4-DCA) ranged from 0.23 ppm to 30.0 ppm in/on rice straw harvested either 67-80 days following the last of two postemergence applications at 4 lb ai/A/application (1X the maximum registered seasonal rate) or 56-58 days following a single postemergence application at 6 lb ai/A (0.75X). Although the maximum residue of 30 ppm found in/on rice straw is much less than the established tolerance of 75 ppm, the Agency is reluctant to recommend for a decreased tolerance

in rice straw without additional data from MS and CA, the states which previously reported tolerance-exceeding residues.

#### Wheat forage, hay, and straw

Adequate wheat forage data (MRID 44768801) are available. In three field trials conducted in ND, spring wheat plants were treated with a single postemergence broadcast application of the 81% DF formulation at 1.14-1.19 lb ai/A (~1X the maximum registered single application rate) using ground equipment. Wheat forage was harvested 24-25 days following treatment when plants were at the Feekes Growth Stage 7 to 9 (stem elongation stage to flag leaf stage). The data-collection method used was EN-CAS Method No. ENC-9/90. Propanil residues (determined as base-releasable 3,4-DCA) ranged from 0.02 to 0.16 ppm in/on six treated samples. Based on these data, the registrant must propose a propanil tolerance for wheat forage at 0.2 ppm, TOX and ORE considerations permitting. The registrant is required to amend propanil labels with registered uses on wheat to specify a pregrazing/preharvest interval of "Feekes Growth Stage 7 to 9 (typically 24-25 days; stem elongation stage to flag leaf stage)" for wheat forage. Finally, product labels with use claims on small grains must be modified to remove the feeding restriction for the grazing of treated crop or cutting for green chop.

Residue data for wheat hay are not available, and these data are required for reregistration.

Wheat straw data (MRIDs 00111370 and 00055546) were reported in the 8/26/87 Residue Chapter. Ten tests were conducted in ND, seven tests in MN, one test in SD, and nine tests in Canada. Wheat plants were treated once with a representative EC formulation at 1.5-2.63 lb ai/A (~1.0-1.75X the maximum permissible label rate) using ground or unspecified equipment. Wheat straw samples were harvested 60-94 days following propanil application. Residues in/on treated straw samples ranged from <0.05-ppm (nondetectable) to 0.41 ppm. Samples were analyzed using the GC method which included a four-hour hydrolysis in 5 N NaOH. Samples collected from the MN tests were reanalyzed using Method II of PAM Volume II; the Chapter reported that maximum residue levels from the reanalysis were up to 250% higher than those found using the 4-hour hydrolysis procedure. Based on these data, the 8/26/87 Residue Chapter reassessed the wheat straw tolerance from 0.75 ppm to 1.5 ppm.

#### GLN 860.1520: Processed Food/Feed

The reregistration requirements for data depicting magnitude of the residue in the processed commodities of barley, oats, rice, and wheat are fulfilled.

#### Barley, oats, and wheat

The requirement for a wheat processing study is waived based on the early-season application timing (4-leaf stage or earlier) and the lack of residues in/on wheat grain (<0.01 ppm) resulting

from a 5X exaggerated rate field trial. The Agency does not expect residues to concentrate in the processed products of wheat. The requirements for processing data on barley and oats are also waived because the registered use patterns of barley and oats are identical to wheat.

### Rice

The 8/26/87 Residue Chapter reported the results of an acceptable rice processing study (MRIDs 00035687 and 00035688). The study showed no concentration of residues in polished rice and average concentration factors of 3.5X for rice hulls and 4.6X for rice bran. The highest average field trial (HAFT) propanil residue in rice is 8.7 ppm (DP Barcode D214322, C. Swartz, 11/16/95). Based on this HAFT and the observed concentration factors, the maximum expected residues are 30.45 ppm for hulls ( $8.7 \times 3.5$ ) and 40.02 ppm for bran ( $8.7 \times 4.6$ ). These expected residues are higher than the reassessed tolerance of 10 ppm for rice grain. Based on these data, the registrants must propose higher tolerances for rice hulls (from 10 ppm to 30 ppm) and rice bran (from 10 ppm to 40 ppm).

### GLN 860.1480: Meat, Milk, Poultry, and Eggs

The reregistration requirements for data depicting magnitude of the residue in meat, milk, poultry, and eggs are fulfilled. The registrant has submitted acceptable ruminant and poultry feeding studies to reassess the adequacy of established propanil tolerances on livestock commodities. A summary of the livestock feeding data relative to the maximum theoretical dietary burdens of propanil to beef cattle, dairy cattle, and poultry is included in this document.

### Maximum theoretical dietary burdens

The potential for secondary transfer of propanil residues to animal commodities exists because the herbicide is registered for use on barley, oats, rice, and wheat; these crops include commodities which may be used as animal feed items. The maximum theoretical dietary burdens of propanil to beef cattle, dairy cattle, and poultry are calculated in the table below.

Maximum dietary burdens of propanil to beef cattle, dairy cattle, and poultry.

Feed Commodity	% Dry Matter <sup>a</sup>	% Diet <sup>a</sup>	Reassessed Tolerance Level (ppm) <sup>b</sup>	Dietary Contribution (ppm) <sup>c</sup>
<b>Beef Cattle</b>				
Rice, grain	88	40	10	4.5
Rice, straw	90	10	75	8.3
Rice, bran	90	15	40	6.7
Wheat, forage	25	25	0.2	0.2
Wheat, straw	88	10	1.5	0.17
<b>TOTAL BURDEN</b>		100		<b>19.87</b>
<b>Dairy Cattle</b>				
Rice, grain	88	40	10	4.5
Rice, straw	90	10	75	8.3
Wheat, forage	25	50	0.2	0.4
<b>TOTAL BURDEN</b>		100		<b>13.2</b>
<b>Poultry <sup>e</sup></b>				
Rice, grain	--	60	10	6.0
Rice, bran	--	25	40	10.0
<b>TOTAL BURDEN</b>		85		<b>16.0</b>

<sup>a</sup> As per Table 1 (OPPTS Guideline 860.1000).

<sup>b</sup> Reassessed level based on data from field trials.

<sup>c</sup> Ruminant contribution = [tolerance ÷ %DM] X %diet and poultry contribution = tolerance X %diet.

<sup>d</sup> Rice hulls and bran are cattle feed items; however, it is assumed that both bran and hulls would not be fed to the same animal. In addition, rice hulls are high in silica and are used with caution in cattle feeding (from personal communication with J. Stokes, 5/15/01).

<sup>e</sup> Rice hulls (15% of poultry diet) and bran are poultry feed items; however, it is assumed that both bran and hulls would not be fed to the same birds simultaneously with rice grain (rough rice). Propanil is also registered on other small grains used in poultry diets (barley, oats, and wheat). As the percent of small grain crop treated with propanil is <1% (per registrant), and the contribution of small grains to the MTDB is negligible compared to rice, these commodities were not included in calculating the MTDB for poultry.

### Ruminant feeding study

An acceptable ruminant feeding study (MRID 44550101) is available. Four groups of Holstein dairy cows were dosed orally once daily following the morning milking for 28 days with either rice-based rations containing field-aged residues at 3.9 ppm (propanil equivalents) or gelatin capsules fortified with propanil at dose levels equivalent to 15, 45, and 150 ppm (mg/kg diet on a dry weight basis). The feeding levels depicted in the study are approximately equivalent to 0.3X (rice-fed), 1.1X, 3.4X, and 11.4X, respectively, the anticipated maximum dietary burden of 13.2 ppm for dairy cattle. Milk samples were collected on Days 0, 1, 3, 7, 11, 14, 18, 21, 24, and 27. It is not apparent as to when residues of propanil in milk plateaued. Maximum propanil residues observed were 0.013 ppm in milk from cows dosed at 3.9 ppm (0.3x) with rice-based

rations bearing aged residues of propanil, and 0.035, 0.050, and 0.144 ppm, respectively, in milk from cows dosed with propanil *per se* by capsule at 15 (1.1x), 45 (3.4x), and 150 ppm (11.4x). Dairy cows were sacrificed within 4-10 hours of the final dose administration. At sacrifice, samples of fat (composite omental and perirenal), muscle (round and loin), liver, and kidney (both) were collected. A GC/NPD method (slightly modified version of EN-CAS Method No. ENC-9/90) was used in the analyses of milk and cattle tissue samples. The data-collection method is adequate for the purpose of data collection based on acceptable method recoveries.

Maximum residues, determined as 3,4-DCA and calculated as propanil, that were obtained from dairy cattle fed at the 15-ppm dosing level (0.75X) were: 0.035 ppm in milk, 0.31 ppm in liver, 0.77 ppm in kidney, <0.05 ppm (nondetectable) in muscle, and 0.10 ppm in fat. Based on the available data, RRB2 concludes that: (i) the established milk tolerance of 0.05 ppm is appropriate; (ii) the established fat tolerance of 0.10 ppm is also appropriate; (iii) the established meat tolerance of 0.1 ppm may be lowered to 0.05 ppm; and (iv) the established meat byproducts tolerance of 0.1 ppm should be increased to 1.0 ppm.

#### Poultry feeding study

An acceptable poultry feeding study (MRID 44748201) is available. Laying hens were dosed orally for 28 consecutive days with either rice-based rations containing field-aged residues at 3.7 ppm (propanil equivalents) or gelatin capsules fortified with propanil at dose levels equivalent to 5, 15, or 50 ppm in the diet. The feeding levels depicted in the study are approximately equivalent to 0.2X (rice-fed), 0.3X, 0.9X, and 3.1X, the maximum theoretical dietary burden (MTDB) for poultry of 16.0 ppm. Eggs were collected twice a day (morning and evening) in the 24-hour period following dosing. Control and treated hens were sacrificed within 16-20 hours of the final dose administration, and samples of liver, composite muscle (thigh and breast), and fat were collected. Egg and tissue samples were analyzed for residues of propanil using a GC/NPD method (modified version of EN-CAS Method No. ENC-9/90). The method was deemed adequate for data collection based on acceptable concurrent method recoveries.

Residues of propanil in eggs plateaued after 7 to 11 days of treatment. Maximum propanil residues, determined as 3,4-DCA and calculated as propanil, were 0.016 ppm in eggs from hens dosed at 3.7 ppm (0.2X) with rice-based rations bearing aged residues of propanil, and 0.050, 0.212, and 0.372 ppm, respectively, in eggs from hens dosed with propanil *per se* by capsule at 5 ppm (0.3X), 15 ppm (0.9X), and 50 ppm (3.1X).

Residues of propanil in liver were 0.080-0.163 ppm in hens fed rice-based rations (0.2X). Residues in liver from hens in the 5 ppm (0.3X), 15 ppm (0.9X), and 50 ppm (3.1X) dose groups were 0.077-0.156, 0.183-0.236, and 0.824-1.755 ppm, respectively. Residues were <0.05 (nondetectable) in muscle from the 0.2X (rice-fed) and 0.3X dose groups, and <0.050-0.076 and 0.087-0.161 ppm, respectively, from the 0.9X and 3.1X dose groups. In fat, propanil

residues were <0.05 ppm (<nondetectable) at the 0.2X (rice-fed), 0.3X, and 0.9X feeding levels, and <0.139-0.348 ppm at 3.1X.

The poultry feeding data suggests that the established propanil tolerances should be increased for eggs (from 0.05 ppm to 0.30 ppm) and meat by-products (from 0.1 ppm to 0.50 ppm). The fat tolerance may be lowered (from 0.1 ppm to 0.05 ppm). The established poultry meat tolerance of 0.10 ppm is appropriate.

#### GLN 860.1400: Water, Fish, and Irrigated Crops

##### Irrigation and potable water

No additional irrigation and potable water data are required for reregistration provided the registrant is willing to establish a 7-day retreatment interval for rice and a 30-day discharge interval for water in treated paddies following application of propanil to rice paddies. A brief summary of this regulatory determination is provided below.

The Task Force previously submitted a rice paddy study (MRIDs 42200401 and 42200501; DP Barcode D175417, 9/2/92; R. Perfetti) to fulfill reregistration requirements for aquatic field dissipation and irrigation/potable water data. The reviewed data indicate that residues of propanil and 3,4-DCA (extractable and base-releasable) declined to nondetectable levels (<0.01 ppm) in rice paddy and discharge water 60 days after propanil was applied according to the maximum registered use pattern. Based on the reviewed data, the Agency initially recommended that propanil products registered for use on rice should be amended: (i) to prohibit discharge of rice paddy water within 60 days of the last application; and (ii) to specify a 14-day retreatment interval. The Agency review concluded that if the registrant complies with the recommended label revisions, this will obviate the need for a maximum contaminant level (MCL) in water and for tolerances in irrigated crops. The Agency also concluded that the current half-mile restriction on discharging water in the vicinity of a potable water intake from flowing or standing water should remain on the labels.

The registrant responded to the Agency review of 9/2/92 by submitting a letter dated 1/28/94 in which they argue that the 14-day retreatment interval and the 60-day water discharge restriction are not acceptable because they would seriously disrupt rice cultural practices. The registrant proposes **no** retreatment interval and a 14-day water discharge interval. The Agency (DP Barcode D200196, 3/25/94, R/ Perfetti) subsequently reevaluated the original study submissions and concluded that, based on the data available, a retreatment interval of 7 days would be acceptable and a water discharge restriction of 30 days would be adequate. These are the minimum intervals which could be accepted. If the registrant cannot accept these restrictions, then additional data supporting the Task Force proposals are required. In lieu of these supporting data, the Agency would classify the application of propanil to rice as an aquatic use and additional residue data would be required to determine an appropriate level in/on water as well as acceptable tolerance levels on irrigated crops.

The registrant has submitted additional information (1994; MRID 43406501) in an effort to persuade the Agency to change its conclusions/recommendations to establish a 7-day retreatment interval for rice and a 30-day discharge interval for water in treated paddies following application of propanil to rice paddies. The Agency has considered the submitted summary of the existing data and scientific literature. With respect to the summary of existing data and scientific literature addressing the non-availability of propanil residues in water, the Agency concludes that the registrant has not provided any new information which would affect our previous recommendation for a 30-day discharge interval. The most compelling information offered by the registrant was the discussion of water management practices for rice production; however, in the absence of residue data supporting a discharge interval of less than 30 day, the Agency cannot at this time recommend in favor of a reduction in the discharge interval. With respect to reducing the retreatment interval, essentially no new data were submitted to support the registrant's proposal, and the Agency reiterates its recommendation that product labels be revised to specify a 7-day retreatment interval for application of propanil to rice.

### Fish

The qualitative nature of the residue in crayfish is adequately understood based on an acceptable crayfish metabolism study (MRIDs 41848901 and 41849101). In the study submitted by the registrant, crayfish were exposed to water containing approximately 1 ppm uniformly ring-labeled [<sup>14</sup>C]propanil for six days. The 1 ppm dose level constituted a 3-50X dose based on expected water residue levels in treated paddies. Samples obtained at sacrifice were abdominal muscle, hepatopancreas, and carcass (shell). Total radioactive residues were 3.461 ppm in abdominal muscle, 48.351 ppm in hepatopancreas, and 8.968 ppm in carcass. Samples were solvent-extracted, and solids from muscle and shells were subjected to enzyme hydrolysis. Following extraction and hydrolysis, bound residues were 11.83% TRR in the carcass, but were less than 3%TRR in muscle and hepatopancreas. Radioactive residues were identified or characterized using TLC and HPLC.

In abdominal muscle, 99.49% of the radioactivity was extractable, while 89.08% of the residue was identified as 3,4-DCA and N-3,4-dichlorophenyl-glucosylamine. In hepatopancreas, 97.28% of the radioactivity was extractable; 3,4-DCA was the major identified metabolite, at 52.47%TRR. A total of 69.14% of the hepatopancreas radioactivity was identified. A total of 88.17% of the carcass radioactivity was extractable; 58.95% of the radioactivity was identified as 3,4-DCA (40.95%TRR) and N-3,4-dichlorophenyl-glucosylamine (12.93%TRR). The results of the crayfish metabolism study indicate that propanil is metabolized to 3,4-dichloroaniline and then to N-3,4-dichlorophenyl-glucosylamine and 4,5-dichloro-2-aminophenol-O-sulfonic acid. The HED Metabolism Committee has determined that the residue to be regulated in crayfish is propanil and residues convertible to 3,4-DCA.

The registrant has submitted adequate data (MRID 43748101) depicting magnitude of the residue in crayfish. Residues of propanil and its metabolites, determined as base-releasable DCA and expressed as propanil equivalents, were <0.01-0.03 ppm in/on the edible portion of



crayfish harvested 7-8 months following two applications of the 4 lb/gal EC formulation at ~4 lb ai/A/application, for a total rate of ~8 lb ai/A (1X the maximum seasonal application rate) to drained rice paddy sites. Based on these data, the registrant should propose a propanil tolerance for crayfish at 0.05 ppm.

Data depicting magnitude of the residue in catfish are not available; however, label restrictions against application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced are established on labels for the 4 lb/gal EC, the 81% DF, and the 80.2% DF formulations (EPA Reg. Nos. 62719-392, 62719-413, and 62719-436, respectively). This catfish farming restriction must be added to all propanil labels with use directions on rice.

#### Irrigated crops

Data depicting magnitude of the residue in irrigated crops are not available. However, adequate label restrictions are established to preclude the need for residue data and tolerances on irrigated crops. The registrant's product labels specify the following restrictions: "Water drained from treated rice fields must not be used to irrigate other crops or released within ½ mile upstream of a potable water intake in flowing water (e.g., river, stream, etc.) or within ½ mile of a potable water intake in a standing body of water, such as a lake, pond, or reservoir."

#### GLN 860.1460: Food Handling

Propanil is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

#### GLN 860.1850: Confined Accumulation in Rotational Crops

An acceptable confined rotational crop study (MRID 42963001) is available. In this study, loam soil was treated with uniformly ring-labeled [<sup>14</sup>C]propanil at 6 lb ai/A (~0.75X the maximum registered seasonal rate for rice, 4.0X the maximum registered seasonal rate for wheat). The rotational crops soybeans and sorghum were seeded in the treated soil at 30-, 157-, and 365-day plant-back intervals. Bermudagrass was seeded at plant-back intervals of 157 and 365 days. Immature (forage) and mature soybean (beans, pods and straw) and sorghum (grain and straw) samples were collected. Bermudagrass was sampled at various intervals throughout the study, but was never allowed to grow to a length of greater than 4 inches. Samples were frozen immediately after harvest.

In soybeans, the highest TRR obtained was 0.40 ppm in the straw from the 30-day plant-back plot. The highest residue in grain sorghum was 0.31 ppm in grain from the 30-day plant-back plot. The TRRs in Bermudagrass ranged from 0.16 to 0.26 ppm (157-day and 365-day plant-

back intervals). Since all crops had TRRs greater than 0.01 ppm in samples harvested at all plant-back intervals, additional fractionation work was performed to determine the nature of the radioactive residues. Residues in/on rotational commodities were solvent-extracted, and the remaining solids subjected to a series of hydrolysis (weak acid followed by a strong base). Radioactive residues in extracts were characterized or identified using TLC and HPLC. None of the radioactive residues in rotational crops were identified; however, the registrant demonstrated that radioactivity in the combined organic extracts of soybeans from all 3 rotations was not propanil. Overall, residues were partially characterized as polar and multicomponent. The study review (DP Barcodes D196301 and D208552, 10/23/95, C. Swartz) concluded that in rotational crops, it is likely that, as in the case of rice, propanil residues were either strongly conjugated or incorporated into macromolecules.

#### GLN 860.1900: Field Accumulation in Rotational Crops

No additional field accumulation data in rotational crops are required for reregistration provided propanil labels are amended to specify a 60-day plant-back interval. Currently, only one propanil end-use product registered to Rohm and Haas has established a plant-back interval; the 80.2% DF formulation (EPA Reg. No. 62719-436) specifies "Do not rotate crops other than rice for 120 days following application."

The Agency review (DP Barcodes D196301 and D208552, 10/23/95, C. Swartz) of the submitted confined rotational crop study cited (R. Cook memo dated 4/24/79) previously reviewed field accumulation data. These data showed no accumulation of propanil residues in rotational crops [barley (grain); corn (grain); lettuce; sugar beets (roots and tops); and sunflower seeds] at a plant-back interval of 2 weeks (1X application rate). Although one soybean sample contained residues of 0.08 ppm, this is considered to be anomalous; however, to assure that no propanil residues of concern would be found in soybeans or any other rotational crop, registered labels should indicate a plant-back interval of 60 days for all rotational crops.

Table B. Residue Chemistry Science Assessments for Reregistration of Propanil.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
860.1200: Directions for Use	N/A = Not Applicable	Yes <sup>2</sup>	See Tables A1 and A2.
860.1300: Plant Metabolism	N/A	No	00035588, 00035589, 00035684, 00036100, 00052347, 00052348, 00052349, 00052350, 42209201 <sup>3</sup> , 42382901 <sup>4</sup> , 42382902 <sup>4</sup> , 43285401 <sup>5</sup> , 43372201 <sup>6</sup>
860.1300: Animal Metabolism	N/A	No	00035697, 00035698, 00035699, 00035905, 00067394, 41754401 <sup>7</sup> , 41755301 <sup>7</sup> , 41848801 <sup>8</sup> , 41848901 <sup>8</sup> , 41849101 <sup>8</sup> , 41983901 <sup>8</sup>
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No	00035587, 00055547, 00067394, 00076113, 00111367, 00111388, 43355201 <sup>9</sup> , 43196001 <sup>10</sup> , 44748202 <sup>11</sup>
- Animal commodities	N/A	No	00055547, 00111367, 44748201 <sup>11</sup>
860.1360: Multiresidue Methods	N/A	No	41755001 <sup>12</sup>
860.1380: Storage Stability Data			
- Plant commodities	N/A	No	00035683, 43157001 <sup>13</sup> , 43157002 <sup>13</sup>
- Animal commodities	N/A	No	44748201 <sup>11</sup>
- Water	N/A	No	42200401 <sup>14</sup> , 42200501 <sup>14</sup>

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
<b>860.1500: Crop Field Trials</b>			
<u>Cereal Grains Group</u>			
- Barley grain	.2 [180.274(a)(1)]	No	00078930
- Oat grain	.2 [180.274(a)(1)]	No	00078930
- Rice	2 [180.274(a)(1)]	No <sup>15</sup>	00035687, 00035688, 42237101 <sup>16</sup> , 42237201 <sup>16</sup> , 43282801 <sup>5</sup>
- Wheat grain and aspirated grain fractions	0.2, grain [180.274(a)(1)]	No	00055546, 00111370, 00111373, 43196002 <sup>10</sup>
<u>Forage, Fodder, and Straw of Cereal Grains Group <sup>17</sup></u>			
- Barley hay and straw	.75, straw [180.274(a)(1)]	Yes <sup>18</sup>	00078930
- Oat forage, hay, and straw	.75, straw [180.274(a)(1)]	Yes <sup>19</sup>	00078930
- Rice straw	75(N) [180.274(a)(1)]	No	00035687, 00035688, 42237301 <sup>16</sup> , 43282801 <sup>5</sup>
- Wheat forage, hay, and straw	0.75, straw [180.274(a)(1)]	Yes <sup>20</sup>	00055546, 00111370, 00111373, 43196002 <sup>10</sup> , 44768801 <sup>21</sup>
<b>860.1520: Processed Food/Feed</b>			
- Barley	None established	No <sup>22</sup>	
- Oats	None established	No <sup>22</sup>	

Table B (continued).

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References <sup>1</sup>
- Rice	10 - bran, hulls, milled fractions, and polishings [180.274(a)(1)] [180.274(a)(2)]	No	00035576, 00035687, 00035688, 00052347, 42417401 <sup>23</sup>
- Wheat	None established	No <sup>22</sup>	
860.1480: Meat, Milk, Poultry, Eggs			
- Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	0.1(N), fat, meat by products, and meat [180.274(a)(1)]	No	00035694, 00035695, 44550101 <sup>21</sup>
- Milk	0.05(N) [180.274(a)(1)]	No	00035694, 00035695, 44550101 <sup>21</sup>
- Fat, Meat, and Meat Byproducts of Poultry	0.1(N), fat, meat by products, and meat [180.274(a)(1)]	No	44748201 <sup>11</sup>
- Eggs	0.05(N) [180.274(a)(1)]	No	44748201 <sup>11</sup>
860.1400: Water, Fish, and Irrigated Crops			
- Irrigation and potable water	None established	No <sup>24</sup>	00035688, 42200401 <sup>14</sup> , 42200501 <sup>14</sup> , 43406501 <sup>25</sup>
- Irrigated crops	None established	No	
- Fish	None established	No <sup>26</sup>	00035692, 00111394, 41848901 <sup>8</sup> , 41849101 <sup>8</sup> , 42301001 <sup>27</sup> , 43748101 <sup>25</sup>
860.1460: Food Handling	None established	N/A	
860.1850: Confined Rotational Crops	N/A	No	42963001 <sup>9</sup>
860.1900: Field Rotational Crops	None established	No <sup>28</sup>	

Table B (continued).

1. **Bolded** references were reviewed in the Residue Chemistry Science Chapter of the Propanil Reregistration Standard dated 8/26/87. All other references were reviewed as noted.
2. Label amendments are required, and details of the required label amendments are presented in the respective endnote under GLNs 860.1500 (Crop Field Trials), 860.1400 (Water, Fish, and Irrigated Crops), and 860.1900 (Field Accumulation in Rotational Crops) of this table.
3. DP Barcode D175312, 4/2/92, J. Abbotts.
4. DP Barcode D180736, 12/14/92, S. Funk.
5. DP Barcode D205676, 9/8/94, C. Swartz.
6. DP Barcode D208555, 11/14/95, C. Swartz.
7. DP Barcode D160814, 2/21/92, C. Olinger.
8. DP Barcodes D164198 and D167950, 3/23/92, R. Perfetti.
9. DP Barcodes D196301 and D208552, 10/23/95, C. Swartz.
10. DP Barcode D203514, 9/22/94, C. Swartz.
11. DP Barcodes D253336 and D253337, 9/10/01, S. Kinard.
12. A study, investigating the behavior of propanil when subjected to FDA's multiresidue protocol C, was submitted to EPA and forwarded to FDA for review.
13. DP Barcode D200811, 10/3/95, C. Swartz.
14. DP Barcode D175417, 9/2/92, R. Perfetti.
15. No additional rice grain data are required; however, based on the available data the registrant is required to revise propanil product labels with use claims on rice to specify a 60-day PHI for grain.
16. DP Barcode D175886, 6/22/92, R. Perfetti.
17. Propanil product labels with use claims on barley, oats, and wheat should be modified to delete the feeding restrictions for the grazing of treated crop or cutting for green chop.
18. Barley hay data are not available; the requested data for wheat hay will be translated to barley hay. Adequate barley straw data are available.
19. Adequate oat straw data are available; however, oat forage and oat hay data have not been submitted. The available data for wheat forage will be translated to oat forage, and the requested data for wheat hay will be translated to oat hay.
20. Adequate wheat forage and wheat straw data are available; however, wheat hay data are required for reregistration. The required wheat hay data should be generated using representative EC and DF formulations of propanil applied according to the maximum registered use patterns. The number and locations of wheat hay field trials should be in compliance with the current applicable OPPTS guideline. Propanil labels with registered uses on wheat should be revised to specify a pregrazing/preharvest interval

Table B (continued).

- of "Feekes Growth Stage 7 to 9 (typically 24-25 days, stem elongation stage to flag leaf stage)" for wheat forage.
21. DP Barcode D276424, 9/10/01, S. Kinard.
  22. The processing data requirements for barley, oats, and wheat are waived. This determination is based on the early-season application timing (4-leaf stage or earlier) and the lack of residues in/on wheat grain (<0.01 ppm) resulting from a 5x exaggerated rate field trial.
  23. DP Barcode D181471, 11/6/92, C. Olinger.
  24. No additional irrigation and potable water data are required provided the registrant is willing to establish a 7-day retreatment interval for rice and a 30-day discharge interval for water in treated paddies following application of propanil to rice paddies.
  25. DP Barcode D276423, 9/10/01, S. Kinard.
  26. All propanil labels with use directions on rice should be amended to specify restrictions against application to fields where catfish farming is practiced and draining water from fields into areas where catfish farming is practiced.
  27. DP Barcode D178275, 9/14/92, R. Perfetti.
  28. All registered propanil labels should be revised to specify a 60-day plant-back interval for all rotational crops.

## TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of propanil in/on plant, animal, and processed commodities are established under 40 CFR §180.274(a)(1) and (a)(2). These tolerances are currently expressed as the combined residues of propanil (3',4'-dichloropropionanilide) and its metabolites (calculated as propanil). The Agency is now recommending that propanil tolerance expression for plant and animal commodities be revised to specify that the residues of concern are propanil and its related compounds convertible to 3,4-DCA.

To eliminate redundancy, the propanil tolerances separately listed under 40 CFR §180.274(a)(1) and (a)(2) should be combined as 40 CFR §180.274(a).

The Agency has updated the list of raw agricultural and processed commodities and feedstuffs derived from crops (Table 1, OPPTS GLN 860.1000). As a result of changes to Table 1, propanil tolerances for certain RACs which have been removed from the livestock feeds table need to be revoked. Also, some commodity definitions must be corrected.

A summary of propanil tolerance reassessments is presented in Table C. Discussions of residue data used for tolerance reassessment are presented in the "Summary of Science Findings" section for GLNs 860.1500 (Crop Field Trials), 860.1520 (Processed Food/Feed), 860.1480 (Meat, Milk, Poultry, and Eggs), and 860.1400 (Water, Fish, and Irrigated Crops).

### Tolerances Listed Under 40 CFR §180.274(a)(1):

Adequate residue data have been submitted (or were translated) to reassess the established tolerances for the following commodities, **as defined**: barley, grain; barley, straw; cattle, fat; cattle, meat by products; cattle, meat; eggs; goats, fat; goats, meat by products; goats, meat; hogs, fat; hogs, meat by products; hogs, meat; horses, fat; horses, meat by products; horses, meat; milk; oat, grain; oat, straw; poultry, fat; poultry, meat by products; poultry, meat; rice; rice, straw; rice bran; rice hulls; sheep, fat; sheep, meat by products; sheep, meat; wheat, grain; and wheat, straw.

The established tolerances for rice mill fractions and rice polishings should be revoked because according to Table 1 of OPPTS GLN 860.1000 these commodities are no longer considered to be significant livestock feed items.

### Tolerances To Be Proposed Under 40 CFR §180.274(a):

Adequate residue data have been submitted (or were translated) for the establishment of propanil tolerances for the following commodities: crayfish and oat and wheat forage.

Inadequate residue data are available for the establishment of propanil tolerances for the following commodities: barley hay; oat hay; and wheat hay. The requested data for wheat hay will be translated to barley hay and oat hay.



Tolerances Listed Under 40 CFR §180.274(a)(2):

The established tolerances for rice bran and rice hulls presently listed under 40 CFR §180.274(a)(2), should be reassigned under 40 CFR §180.274(a) for the purpose of tolerance reorganization. These tolerances are duplicates of the established tolerances for the same commodities listed in 40 CFR §180.274(a)(1).

Table C. Tolerance Reassessment Summary for Propanil.

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment [Correct Commodity Definition]
<b>Tolerance Listed Under 40 CFR §180.274(a)(1)</b>			
Barley, grain	.2	0.20	
Barley, straw	.75	1.5	
Cattle, fat	0.1(N)	0.10	
Cattle, meat by products	0.1(N)	1.0	
Cattle, meat	0.1(N)	0.05	
Egg	0.05(N)	0.30	
Goat, fat	0.1(N)	0.10	
Goat, meat by product	0.1(N)	0.80	
Goat, meat	0.1(N)	0.05	
Hog, fat	0.1(N)	0.10	
Hog, meat by product	0.1(N)	0.80	
Hog, meat	0.1(N)	0.05	
Horse, fat	0.1(N)	0.10	
Horse, meat by product	0.1(N)	0.80	
Horse, meat	0.1(N)	0.05	
Milk	0.05(N)	0.05	
Oat, grain	.2	0.20	
Oat, straw	.75	1.5	
Poultry, fat	0.1(N)	0.05	
Poultry, meat by products	0.1(N)	0.50	
Poultry, meat	0.1(N)	0.10	
Rice	2	10	[Rice, grain]
Rice bran	10	40	[Rice, bran]
Rice hulls	10	30	[Rice, hull]
Rice mill fractions	10	Revoke	These items have been deleted from Table 1 of OPPTS GLN 860.1000.
Rice polishings	10	Revoke	
Rice, straw	75(N)	75	

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Table C (continued).

Commodity	Established Tolerance (ppm)	Reassessed Tolerance (ppm)	Comment [Correct Commodity Definition]
Sheep, fat	0.1(N)	0.10	
Sheep, meat by products	0.1(N)	0.80	
Sheep, meat	0.1(N)	0.05	
Wheat, grain	0.2	0.20	
Wheat, straw	0.75	1.5	
<b>Tolerances To Be Proposed Under 40 CFR §180.274(a)(1)</b>			
Barley, hay	None	TBD <sup>1</sup>	The requested data for wheat hay will be translated to barley hay.
Crayfish	None	0.05	
Oat, forage	None	0.20	The available data for wheat forage will be translated to oat forage.
Oat, hay	None	TBD	The requested data for wheat hay will be translated to oat hay.
Wheat, forage	None	0.20	
Wheat, hay	None	TBD	Additional data are required.
<b>Tolerance Listed Under 40 CFR §180.274(a)(2)</b>			
Rice bran	10	Reassign	Duplicate tolerances for rice commodities; see 40 CFR §180.274(a)(1).
Rice hulls	10	Reassign	
Rice mill fractions	10	Reassign	
Rice polishings	10	Reassign	

<sup>1</sup> TBD = To be determined. Reassessment of tolerance(s) cannot be made at this time because additional data are required.

### CODEX HARMONIZATION

No Codex MRLs have been established for propanil; therefore, issues of compatibility between Codex MRLs and U.S. tolerances do not exist.

### DIETARY EXPOSURE ASSESSMENT

Anticipated residues of propanil in food commodities and dietary exposure estimates will be assessed in a separate memorandum.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CB No.: 4053  
DP Barcode: None  
Subject: Propanil Registration Standard - Response to Data Call-In Notice on Rice Metabolism. EPA Registration Nos. 707-108 and 707-181.  
From: F. Griffith  
To: R. Taylor and Toxicology Branch  
Dated: 8/4/88  
MRID(s): None

CB No.: 5110  
DP Barcode: None  
Subject: EPA Reg. Nos. 62719-386 and 62719-404. Stam(PEDE). Letter of 2/21/89: Request for Data Waivers.  
From: R. Quick  
To: R. Taylor/J. Miller  
Dated: 4/6/89  
MRID(s): None

CB No.: 5875  
DP Barcode: None  
Subject: Propanil: Data Gaps regarding FDA's Multiresidue Methods (MRM) Testing Requirements Specified in the Propanil Registration Standard.  
From: W. Chin  
To: L. Rossi  
Dated: 10/23/89  
MRID(s): None

CB No.: 5191  
DP Barcode: None  
Subject: Propanil Registration Standard - Response to Data Call-In Notice on Rice Metabolism and Crayfish Metabolism. EPA Registration Nos. 707-108 and 707-181.  
From: F. Griffith  
To: R. Taylor  
Dated: 10/25/89  
MRID(s): None

CB No.: None  
DP Barcode: None  
Subject: Propanil Registration Standard - Revised Labeling.  
From: W. Waldrop  
To: R. Quick  
Dated: 3/28/90  
MRID(s): None

CB No.: None  
DP Barcode: None  
Subject: Propanil Registration Standard. Clarification of Revised Labeling Requirements.  
From: F. Griffith  
To: W. Waldrop  
Dated: 4/11/90  
MRID(s): None

CB No.: 6442  
DP Barcode: None  
Subject: Propanil Registration Standard. Magnitude of the Residue in/on Rice, Processed Products of Rice, Irrigation water and Crayfish; Field Study Protocols.  
From: H. Fonouni  
To: B. Baker and R. Engler  
Dated: 4/18/90  
MRID(s): None

CB No.: 6835  
DP Barcode: None  
Subject: ND900004. Section 24(c) Stampede CM (Propanil plus MCPA) on Oat Crops.  
From: A. Aikens  
To: R. Taylor/V. Walters  
Dated: 10/5/90  
MRID(s): None

CB No.: 7101  
DP Barcode: None  
Subject: Propanil Registration Standard - Review of NPC Comments.  
From: F. Griffith  
To: T. Stowe  
Dated: 12/14/90  
MRID(s): None

CB No.: 7665  
DP Barcode: None  
Subject: Reregistration of Propanil. EPA Reg. Nos. 62719-386 and 62719-404.  
Request for Data Waiver.  
From: P. Deschamp  
To: R. Engler and L. Rossi  
Dated: 4/12/91  
MRID(s): None

CB No.: None  
DP Barcode: None  
Subject: Multiresidue Method (MRM) test information for updating PAM I,  
Appendix I.  
From: P. Deschamp  
To: L. Sawyer, FDA  
Dated: 4/23/91  
MRID(s): 41755001

CB No.: 7015  
DP Barcode: D155458  
Subject: Reregistration of Pronamide. Review of Rohm and Haas Company data  
submissions.  
From: P. Deschamp  
To: K. Farmer  
Dated: 8/28/91  
MRID(s): 41570101 and 41570102

CB No.: 8703  
DP Barcode: D157863  
Subject: Reregistration of Propanil: Interim Rice Metabolism Study; Chemical No. 28201.  
From: C. Olinger  
To: L. Rossi/T. Stowe  
Dated: 2/14/92  
MRID(s): None

CB No.: 7622  
DP Barcode: D160814  
Subject: Propanil: Propanil Task Force Response to the Reregistration Standard: Residue Chemistry Data.  
From: C. Olinger  
To: L. Rossi  
Dated: 2/21/92  
MRID(s): 41755001 and 41755301

CB Nos.: 7960 and 8522  
DP Barcodes: D164198 and D167950  
Subject: Propanil Task Force: Response to the Propanil Reregistration Standard: Animal Metabolism Studies.  
From: R. Perfetti  
To: W. Burnam and L. Rossi  
Dated: 3/23/92  
MRID(s): 41848801, 41983901, 41848901, and 41849101

CB No.: 9528  
DP Barcode: D175312  
Subject: Reregistration of Propanil. Wheat Metabolism Study.  
From: J. Abbotts  
To: T. Stowe  
Dated: 4/2/92  
MRID(s): 42209200 and 42209201

CB No.: 9807  
DP Barcode: D177583  
Subject: Propanil. Case # 0226. Method Validation for Poultry Metabolism Study.  
From: L. Cheng  
To: T. Stowe/W. Waldrop  
Dated: 5/27/92  
MRID(s): None

CB No.: 9589  
DP Barcode: D175886  
Subject: Response to the Propanil Reregistration Standard: Residue Data.  
From: R. Perfetti  
To: W. Burnam and L. Rossi  
Dated: 6/22/92  
MRID(s): 42237101, 42237201, and 42237301

CB No.: 9541  
DP Barcode: D175417  
Subject: Response to the Propanil Reregistration Standard: Residue Chemistry.  
From: R. Perfetti  
To: L. Rossi and E. Saito  
Dated: 9/2/92  
MRID(s): 42200401 and 42200501

CB No.: 9876  
DP Barcode: D178275  
Subject: Response to the Propanil Reregistration Standard: Residue Chemistry.  
From: R. Perfetti  
To: L. Rossi and E. Saito  
Dated: 9/14/92  
MRID(s): 42301001

CB No.: 10362  
DP Barcode: D181471  
Subject: Reregistration of Propanil. Rice Processing Study: Chemical No. 28201.  
From: C. Olinger  
To: L. Rossi  
Dated: 11/6/92  
MRID(s): 42417401

CB No.: 10448  
DP Barcode: D181822  
Subject: Reregistration of Propanil. 171-4(a): Nature of the Residue in Wheat.  
Plan to Upgrade Study.  
From: S. Funk  
To: L. Rossi/T. Stowe  
Dated: 11/16/92  
MRID(s): None

CB No.: 10228  
DP Barcode: D180736  
Subject: Reregistration of Propanil. 171-4(a): Nature of the Residue in Rice..  
From: S. Funk  
To: L. Rossi/T. Stowe  
Dated: 12/14/92  
MRID(s): 42382900-42382902

CB No.: 10683  
DP Barcode: D183249  
Subject: Response to the Propanil Reregistration Standard: Residue Chemistry  
From: R. Perfetti  
To: Lois Rossi and E. Saito  
Dated: 1/5/93  
MRID(s): None

CB Nos.: 11291 and 11275  
DP Barcodes: D187325 and D187530  
Subject: Response to the Propanil Reregistration Standard: Residue Chemistry  
From: R. Perfetti  
To: L. Rossi and E. Saito  
Dated: 3/3/93  
MRID(s): None



CB No.: 11742  
DP Barcode: D190259  
Subject: Propanil. Registrants Response to CBRS Review of Wheat Metabolism Study. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
From: F. Fort  
To: E. Feris/W. Waldrop  
Dated: 11/30/93  
MRID(s): None

CB No.: 13332  
DP Barcode: D200196  
Subject: Response to the Propanil Reregistration Standard: Residue Chemistry.  
From: R. Perfetti  
To: L. Rossi  
Dated: 3/25/94  
MRID(s): None

CB No.: None  
DP Barcode: None  
Subject: Propanil. List A Reregistration Case No./Chemical ID No. Meeting with Rohm and Haas and the Propanil Task Force Regarding the Retreatment Interval for Rice and the Holding Period for Water in Treated Paddies, 6/9/94.  
From: C. Swartz  
To: W. Waldrop  
Dated: 6/23/94  
MRID(s): None

CB No.: 14030  
DP Barcode: D205676  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201. Propanil Task Force Submission to Upgrade a Rice Metabolism Study [Guideline Ref. No. 171-4(a)] and Rice Field Trials [Guideline Ref. No. 171-4(k)].  
From: C. Swartz  
To: E. Saito  
Dated: 9/8/94.  
MRID(s): 43285401 and 43282801

CB No.: 13729  
DP Barcode: D203514  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Rohm and Haas Submission of Wheat Residue and Method Validation  
Data.  
From: C. Swartz  
To: W. Waldrop  
Dated: 9/22/94  
MRID(s): 43196001 and 43196002

CB No.: 13433  
DP Barcode: D200811  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Propanil Task Force Submission of Storage Stability Data in Rice  
[Guideline Ref. No. 171-4(e)].  
From: C. Swartz  
To: W. Waldrop  
Dated: 10/3/95  
MRID(s): 43157001 and 43157002

CB Nos.: 12739 and 14594  
DP Barcodes: D196301 and D208552  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Propanil Task Force Submission of a Confined Rotational Crop Study,  
and a Method Radiovalidation Study for Rotational Crop Matrices  
[Guideline Ref. No. 165-1].  
From: C. Swartz  
To: W. Waldrop  
Dated: 10/23/95  
MRID(s): 42963001 and 43355201

CB No.: 14597  
DP Barcode: D208555  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Rohm and Haas Submission to Upgrade a Wheat Metabolism Study  
[Guideline Ref. No. 171-4(a)]  
From: C. Swartz  
To: W. Waldrop  
Dated: 11/14/95  
MRID(s): 43372201

CB No.: 15461  
DP Barcode: D214322  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Propanil Task Force request for guidance concerning tolerances in or on  
rice grain and straw.  
From: C. Swartz  
To: W. Waldrop  
Dated: 11/16/95  
MRID(s): None

CB No.: None  
DP Barcode: None  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Issues to be presented at the 12/19/95 meeting of the HED Metabolism  
Committee.  
From: C. Swartz  
To: HED Metabolism Committee  
Dated: 12/8/95  
MRID(s): None

CB No.: 16777  
DP Barcode: D222631  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Outcome of the 1/16/96 meeting of the HED Metabolism Committee.  
From: C. Swartz  
To: HED Metabolism Committee  
Dated: 2/6/96  
MRID(s): None

CB No.: 17053  
DP Barcode: D224402  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Protocol: Propanil Task Force Proposal to Satisfy GLN 171-4(j),  
Magnitude of the Residue in Meat and Milk.  
From: C. Swartz  
To: K. Davis  
Dated: 4/10/96  
MRID(s): None

CB No.: None  
DP Barcode: D253336 and D253337  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Poultry Feeding Study and Independent Laboratory Validation (ILV) Trial  
For a GC Method Used to Determine Residues of Propanil in Rice.  
From: S. Kinard  
To: Tom Myers  
Dated: 9/10/01  
MRID(s): 44748201 and 44748202

CB No.: None  
DP Barcode: D276423  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Magnitude of the Residue Study in/on Crayfish and Response to the  
Agency's Request for the Establishment of Retreatment and Discharge  
Intervals for Propanil Use in Rice Culture.  
From: S. Kinard  
To: Tom Myers  
Dated: 9/10/01  
MRID(s): 43406501 and 43748101

CB No.: None  
DP Barcode: D276424  
Subject: Propanil. List A Reregistration Case No. 0226/Chemical ID No. 028201.  
Magnitude of the Residue Study in/on Wheat Forage and Ruminant  
Feeding Study.  
From: S. Kinard  
To: Tom Myers  
Dated: 9/10/01  
MRID(s): 44768801 and 44550101

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00035588 Briner, R.C.; Vervynck, D.J.; Lippman, A.E.; et al. (1970) Final Report on Rogue Residues: Identification and Analysis: Part II--Identification of Insoluble Metabolites: Agricultural Research and Development Report No. 183. (Unpublished study received Sep 18, 1971 under 1F1036; submitted by Monsanto Co., Washington, D.C.; CDL:091920-M)

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00035688 Cherry, W.F.; Johnson, W.H.; Owens, F.C.; et al.(1967) ?Residues of Stam F-34 on Rice|. (Unpublished study received Jun 11, 1970 under 0F0932; submitted by Rohm & Haas Co., Philadelphia, Pa.;CDL:091589-A)

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00035905 Gabriel, K.L. (1965) Feeding of Radioactive Stam to Cattle and Chickens: Project # 20-122. (Unpublished study received Jun 11, 1970 under 0F0932; prepared by A.M.E. Associates, submitted by Rohm & Haas Co., Philadelphia, Pa.; CDL:091589-M)

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